IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) Art Unit: 1625
BERG, Kurt Frimann	Examiner: SOLOLA, T.
Serial No.: 10/532,341) Washington, D.C.
Filed: April 22, 2005) September 20, 2007
For: PHARMACEUTICAL COMPOSITIONS COMPRISING) Docket No.: BERG=3
FLAVONOIDS) Confirmation No.: 1525

ELECTION WITH TRAVERSE

U.S. Patent and Trademark Office Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir:

In response to the restriction requirement mailed July 27, 2007, Applicant responds as follows.

- 1. Applicant elects group I (claims 1-27) with traverse.
- 2. In response to OA §4, Applicants make the following species elections, with traverse:
- (a) as a set of compounds, the <u>rutosides</u> of claim 19. For these compounds, the R3 of claim 16 is -O- rutinose.
- (b) as the single compound, <u>troxerutin</u>, the structure of which is set forth on page 18.

Comparing the structure of troxerutin with the general formulae of claim 16, we can see that troxerutin corresponds to the first formula, with the following identities:

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R8, -H
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R7, $-O-CH_2CH_2-OH$

R6, -H

R5, -OH

R3, -O-rutinose

R6', H

R5', $-O-CH_2CH_2-OH$

R4', -O-CH₂CH₂-OH

R3', H

R2', H

The points of attachment of these functional groups are as set forth in the first formula of claim 16.

- 3. Since there is the possibility of reinstatement or rejoinder of group II, in response to OA §3 we elect with traverse, as the method of use, that of claim 58. If further specificity is required, we elect treatment of a condition relating to common cold (59), and if need be, common cold of upper and/or lower respiratory tract and/or eyes (60). If we are required to elect the nature of the infection, we elect viral infections (61), and if further specificity is required, conditions caused by or associated with the viruses of claim 65 and, more specifically, claim 66. If still more specificity is required, we elect treatment of conditions caused by or associated with rhinoviruses.
- 4. If all restrictions are maintained, then at least claims 1-17, 19, 21, 23-25, and 27 read upon the elected invention. We are assuming at this time that "troxerutin" is naturally occurring and thus excluded by claim 18.
- 5. We traverse the group-level restriction on the ground that the Examiner has applied the wrong legal standard.
- 5.1. This application is the national stage of PCT/DK2003/000608, and consequently PCT unity rules apply. See 37 CFR 1.499 and MPEP 1893(d).

It is evident that the Examiner applied the wrong legal standard because

- (1) there is no reference to the standard of PCT rule 13 or to 37 CFR 1.499, and
- (2) the restriction refers to 35 USC 121 and MPEP 806.04, 808.01, 806.05(h), all of which define <u>domestic</u> restriction practice.
- 5.2. Applicants should not be penalized because of the PTO's error. In particular, they should not lose the opportunity to obtain a first office action on the merits as the next action in this case (preferably mailed prior to November 1, 2007) as a

result of the PTO's error.

If the PTO, reviewing the claims under PCT unity practice, decides that restriction is improper, then of course it should proceed directly to FOAM, as there would be no reason for delay -- the FOAM would simply withdraw the current restriction.

If the PTO decides that there is basis under PCT unity rules for <u>reimposing</u> the group-level restriction and/or the species restrictions, it might ordinarily mail just a new restriction requirement rather than a FOAM.

Applicants, while traversing the restriction, waives the right to receive such a new restriction requirement in advance of FOAM. Applicant advises the examiner that if he will be reimposing the already stated group-level restriction and/or species restrictions under PCT unity rules, that Applicants makes the same elections (with traverse). Note that under the PTO's telephone restriction practice, they may elect with traverse in advance of a formal restriction requirement, without making a statement of the reason for the traversal, and this allows the PTO to proceed directly to a FOAM. We are simply saving the Examiner the trouble of making the phone call.

If the PTO wishes to make, under PCT unity rules, a restriction which is substantially different from the one already imposed, so that it is unclear what Applicants would elect, Applicants request that the Examiner call counsel under telephone restriction practice in order to expedite examination.

5.3. Applicants wish to note that under PCT unity rules, a composition and its method of use are normally examined together. See PCT Administrative Instructions, Annex B, paragraph (d)(1), and 37 CFR 1.475(b)(2) and MPEP 1850(A).

The principal exception is when there is a problem of \underline{a} posteriori lack of unity, that is, prior art is found which appears to anticipate or render obvious the composition as claimed. See Annex B, paragraph (c)(i)-(ii).

Likewise, under PCT rules, dependent claims directed to species are usually all examined. See Annex B, paragraph (c)(i).

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The exception is when there is a problem of <u>a posteriori</u> lack of unity with the genus claim. See (c) (ii).

Hence, the restrictions should be re-imposed if and only if, in course of a prior art search, the Examiner finds art destroying the patentability of the generic composition claim.

6. The species restrictions are traversed on the grounds that (1) the wrong legal standard was applied, see 5.1 above, and (2) generic claims are allowable.

Respectfully submitted,

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